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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/742,344	12/19/2003	Karl Lintner	SEDERM 3.0-002	6240
530 7590 08/17/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER NIEBAUER, RONALD T	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 08/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/742,344

Applicant(s)

LINTNER ET AL.

Examiner

Ronald T. Niebauer

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-24, 29, 30, 33 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-28, 31, 32, 34-36 and 38 is/are rejected.
- 7) ☒ Claim(s) 7 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of the species of n-stearoyl-dihydrosphingosine (also known as n-stearoyl-sphinganine) for the ceramide; surfactant for the additional ingredient; Biot-VGVAPG for the polypeptide; and solution for the form in the reply filed on 6/5/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22,23,24,29,30,33,37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/5/07. Specifically, the claims are withdrawn as being drawn to a nonelected additional ingredient (claims 22,30), polypeptide (claims 23,24,29,37), or form (claim 33).

Claims 1-21,25-28,31-32,34-36,38 are under consideration.

In the course of searching for the elected species other prior art to nonelected species was uncovered and is cited herein. It is noted that the claims have been examined with regard to the elected species, not the complete genus of species claimed. Compliance with, for example, 35 USC 112 1st paragraph (written description) has only been considered with regard to the elected species and not to the complete genus of species claimed.

Claim Objections

Claims 7,16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In the instant claims, language such as 'wherein xxx' do not limit the scope of the claim because the claims do not limit the base claim in either structural or compositional matters.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademarks (such as BIOPEPTIDE EL and MATRIXYL page 2) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/26/04 has been considered by the examiner. It is noted that only an abstract has been provided for the foreign patent document identified as JP-JP 2000 136124.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21,25,28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 28, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 25 recites 'human in need of same'. There is insufficient antecedent basis for the term 'same' in the claim. The claim initially recites 'skin aging', but it is not clear why a human would be in need of skin aging.

Claim 21 recites what appears to be alternatives which typically are linked by the term 'or' (compare claim 33) or by a Markush type grouping (compare claim 34). However, by linking the alternatives with 'and' the claim is unclear as to whether the ingredients are alternatives or if all ingredients are included in the composition. For purposes of examination, the claim has been treated as if the ingredients are listed as alternatives.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 28,31, are rejected under 35 U.S.C. 102(a) as being anticipated by Seiberg et al. (US 2002/01927219 as cited in the IDS).

Briefly, claims 28 and 31 are drawn to a cosmetic composition comprising a polypeptide of a particular formula.

Seiberg et al. teach peptide compositions for cosmetic application (claim 1) including peptides (section 0017) such as Stearatoyl-Val-Gly-Val-Ala-Pro-Gly-OH (claim 3) which meets the limitations of the current claim proviso since R₁ is not palmitoyl or H. The composition includes at least one other ingredient, a pigment (claim 1), and the amount of peptide ranges from 0.001%-10% by weight (section 0030).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-21,25-28,31-32,34-36,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiberg et al. (US 2002/01927219 as cited in IDS), Lintner (US 6,620,419), and Cauwet-Martin et al. (US 5,830,481).

Seiberg et al. teach peptide compositions (claim 1) including peptides (section 0017) such as H₂-Val-Gly-Val-Ala-Pro-Gly-NH₂ and Palmitoyl-Val-Gly-Val-Ala-Pro-Gly-OH (claim 3), for cosmetic applications. Seiberg et al. teach that the topical composition can further comprise ceramides and surfactants (section 0051-0052). Seiberg et al. teach that the composition can be in the form of a solution (section 0034-0035) and the amount of peptide ranges from 0.001%-10% by weight (section 0030). Further, Seiberg et al. teach a topical administration of the peptide containing composition to the skin (claim 15). Specifically, compositions were applied topically twice a day (section 0066).

The difference between the teachings of Seiberg and the instant claims, is that Seiberg does not teach the specific ceramides such as n-stearoyl-dihydrosphingosine or the particular ratios between ceramide and the peptide. Seiberg does not teach biotinylated peptides. Seiberg does not teach one specific embodiment involving all recited combinations or specific composition ratios or dosages.

Lintner teach cosmetic compositions of peptides (claim 4). The peptides include chemical modifications at the N-terminus to enhance their activity, stability and to increase their lipophilicity (abstract). Examples of such modifications include addition of a palmitoyl group

(claim 1) or a biotin group (claim 4). Lintner teach a method of using the composition to inhibit the development of wrinkles (claim 16).

Cauwet-Martin et al. teach a cosmetic composition containing a ceramide and a peptide (claim 1). Specifically, the ceramide n-stearoyl-dihydrosphingosine (also known as n-stearoyl-sphinganine) is taught in claim 1. The concentration by weight of the peptide to ceramide is taught to range from 1.5 to 10 (for example claim 9) such that the ceramide is provided in an amount that is greater than the polypeptide. Cauwet-Martin et al. teach a method of administering to the skin (claim 17). Cauwet-Martin et al. teach the use of surfactants in the composition (column 2 line 42), use as a solution (claim 1), and a composition containing at least one other ingredient such as water.

Taken together, it would have been obvious to one of skill in the art use the prior art elements taught by Seiberg, Lintner, and Cauwet-Martin because the ingredients are all used for cosmetic compositions. One would have had a reasonable expectation for success since the elements are disclosed for the same use as cosmetics.

Based on each of the three references, one of skill in the art would have been motivated to combine the disclosed elements to yield predictable results since the combination of elements are all recognized to be useful in cosmetic compositions. Further, one would have had reason to pursue the known options within his or her grasp. Specifically, Seiberg teach Palmitoyl-Val-Gly-Val-Ala-Pro-Gly-OH for use in cosmetics. Since Lintner teach that either a palmitoyl group or a

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biotin group can be used at the N-terminus to enhance activity, stability, and lipophilicity one would have been motivated to obtain the polypeptide of the current invention Biotin-Val-Gly-Val-Ala-Pro-Gly-OH. Further, the other elements such as the specific ceramide (n-stearoyl-dihydrosphingosine) taught by Cauwet-Martin are all present in the prior art and taught as useful for cosmetic compositions. Therefore, the combinations would have yielded predictable results to one of skill in the art at the time of the invention.

The references do not teach one specific embodiment involving all recited combinations or specific composition ratios or dosages. It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. composition ratios and dosages), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2145.05).

Briefly, the claims are generally drawn to a cosmetic composition and method of treatment. Regarding claim language, it is noted that section 2106 of the MPEP states:

Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

In the instant claims, language such as 'having anti-aging activity' and 'capable of providing xxx' do not limit the scope of the claim.

Conclusion

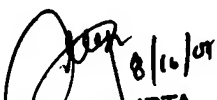
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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PRIMARY EXAMINER